

**TITLE:** Treatment Agreements, Informed Consent and the Role of State Medical Boards in Opioid Prescribing

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**ABSTRACT:** Prescription opioid abuse has reached epidemic proportions in the United States. As a result, states have implemented policies to help reduce prescription opioid abuse and misuse through prescribing rules enforced by state licensing boards. In at least one state, the medical board has mandated the use of treatment agreements for any patients receiving opioid medications from their physicians. These agreements require physicians to urine or saliva test patients annually for drug abuse and to engage in pill counts or other methods of determining drug abuse and allow for those findings to be turned over to law enforcement, if necessary. Treatment agreements, particularly those containing these provisions, should not be adopted by state medical boards. The negative effects on the physician-patient relationship and trust in the medical encounter and the lack of evidence to suggest agreements will be effective in reducing prescription drug abuse do not support their use as a population-based strategy to prevent prescription opioid abuse.

**KEYWORDS:** Ethics, Informed Consent, Pain Management, Opioids

## **Introduction**

The statistics regarding prescription drug overdose in the United States are shocking and clear. One hundred people die from prescription drug overdoses every day in the United States, with three out of four of these drug overdoses caused by prescription painkillers. Prescription drug deaths are, however, just the tip of the iceberg. For every death from prescription pain killers 10 people are admitted to treatment for drug abuse, 32 emergency department visits take place, and 130 people abuse these drugs or are dependent upon them. (1) Notably, while 70% of people who abuse prescription pain medication report that they obtained the drugs from friends or relatives (2), long-term abusers of opioid pain relievers are most likely to acquire their drugs through a prescription from a physician (3).

In addition to the chronic pain and the prescription drug abuse epidemics that are well-documented in the United States, another third interrelated epidemic is now requiring attention as well. Widespread opioid pain reliever abuse has been associated with a dramatic rise in heroin use in the United States. In March 2014, United States Attorney General Eric Holder noted this connection, while raising concern about the “urgent public health crisis”--a 45% increase in U.S. heroin overdose deaths from 2006 to 2010. (4) The Food and Drug Administration (FDA) recently has taken actions that both acknowledge these trends and raise new concerns. In October 2013, the agency recommended that many prescription opioids be reclassified as Schedule II drugs. (5) Later that month, the FDA approved for use a powerful new, pure hydrocodone painkiller, Zohydro ER, leading to an outcry from at least 28 state Attorneys General and medical experts concerned about the medication’s potential for diversion and abuse. (6)

## **State Responses to Opioid Abuse**

As a response to this epidemic of prescription opioid deaths and abuse, many state medical boards have moved to more tightly control access to prescriptions for pain control. This population-based strategy is designed to cut prescription opioids off at their source by making it more difficult for physicians to prescribe them and indirectly for patients to access them. Two primary tools have been used at the state level to do this: prescription drug monitoring programs (PDMPs) and state licensure rules for prescribing physicians. PDMPs have been implemented or passed into law in 48 of 50 states (7) and have been lauded as a key tool in preventing prescription drug abuse. However, studies have shown that use of PDMP data by health care providers is rare (8) which may be due to a lack of funding, implementation problems and limited access to these systems by providers.

Given the problems with PDMPs in many states, state medical licensing boards have promulgated new rules for prescribing physicians. One example of this can be found in the Medical Licensing Board of Indiana (MLBI) proposed emergency rules for prescribers that became effective December 15, 2013. (9) These new rules require all patients receiving opioid prescriptions outside hospice or palliative care settings for longer than 3 consecutive months to sign a “treatment agreement.” Such agreements, as specified by the Indiana emergency rules, authorize mandatory periodic drug testing, the conducting of

random pill counts, and other measures of treatment compliance for patients receiving opioid treatment. (10)

These proposed regulations are consistent with the Federation of State Medical Boards' (FSMB) July 2013 revision of the "Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain" which recommends the use of treatment agreements, including provisions for drug testing and other compliance measures, when prescribing opioids for chronic pain. Although the FSMB policy was only a recommendation, we believe that the effects of this merging of consent and treatment agreement language can already be seen in policies like the new emergency rules for prescribers in Indiana, as well as the implementation guidance for the new rule offered by the Indiana Prescription Drug Abuse Prevention Task Force's Education Committee in its provider toolkit on opioid prescribing which offers suggestions for "informed consent and treatment agreement templates." (11)

### **Shortcomings of Opioid Treatment Agreements as a Prescription Drug Abuse Prevention Strategy**

In light of the statistics noted above, we stipulate that opioid prescribing for chronic, non-terminal pain should be used only after all non-pharmacologic approaches have been exhausted. Moreover, we agree that a population-based strategy to detect and prevent opioid diversion and misuse is necessary. The public health impetus of mandating treatment agreements is clear: to deter and detect misuse, abuse, and diversion of prescription drugs by requiring patients to agree certain conditions for opioid treatment. But the approach proposed in the Indiana rules, and by extension by FSMB, which mandates the blanket use of treatment agreements with mandatory compliance monitoring is both too blunt and too narrow to achieve the desired effect. Therefore, we strongly disagree with the use of treatment agreements for opioid prescribing which mandate pill counting, drug testing, and that waive physician-patient privilege and confidentiality to submit patient records to law enforcement. These provisions are not evidence based, will have a deleterious effect on the physician-patient relationship, and have the potential to undermine legitimate informed consent processes. They also may, as has been alleged by the ALCU of Indiana, constitute illegal search and seizure if the results of such inquiries are turned over to law enforcement. (12) For these reasons, and a few others discussed below, we argue that a contractual approach to opioid therapy consent and compliance be abandoned in favor of a more robust informed consent process accompanied secondarily with appropriate documentation.

*Lack of Evidence.* The lack of evidence regarding the efficacy of treatment agreements, including those with urine testing and other compliance provisions, is a serious problem for pain management physicians and researchers. First, the field suffers from a lack of definitional clarity regarding key terminology such as abuse, misuse, addiction and agreements. (13) Despite the endorsements of treatment agreements by FSMB and others of treatment agreements as an important part of chronic pain management, this consensus is not evidence-based as many authors have noted. Systematic reviews have found weak evidence supporting the use of opioid treatment agreements and urine testing for either primary care or pain clinics. (14) Limited empirical evidence exists to demonstrate that

treatment agreements are effective in preventing medication misuse, abuse or diversion of opioids. (15) In fact, in cases where treatment agreements are used, studies report that patients are often unaware that they have signed such documents, (16) making it difficult for these agreements to have an impact on behavior. Empirical research has shown that agreements are inconsistently used by providers, ranging from 4% (17) to 42%(18) of primary care populations. Others have argued that there is “insufficient evidence to support the universal deployment of [opiate treatment agreements]..... and they can pose a fundamental risk of damaging the therapeutic benefit of the patient-physician relationship.” (19) Similarly Gourley and Heit note that “overreliance on urine drug testing can introduce mistrust into the therapeutic relationship.”

*Harm to the Physician-Patient Relationship.* Proposals like that of the MLBI and FSMB risk radically changing the dynamic between physicians and many patients with pain, a relationship that often is on tenuous grounds from the start. Many patients living with pain have already experienced stigmatization and shaming as a result of their diagnoses (20) and are likely to enter any medical encounter with prejudice or mistrust. It is likely that patients will increasingly fear or avoid opioid therapy, even when it is medically indicated and/or efficacious. Concerns about mandatory testing, use of test results by law enforcement, and other unintended consequences of being prescribed opioid therapy may result in patients avoiding effective therapies. Policies like these will only exacerbate this mistrust of the medical system and their providers for chronic pain patients.

Policies that further constrain medical encounters with pain patients are likely to exacerbate, from the physician perspective, an environment where physicians are necessarily suspicious of patients needing pain management that ultimately might include opioid treatment. Physician fear of opioid prescribing is long-standing (21), and we believe that policies such as these might further discourage such treatments, even where opioid treatment is appropriate, in order to prevent increasing the risk of potential for physician censure or license suspension.

*Conflating Informed Consent and Contract.* In addition to recommending treatment agreements generally, FSMB also suggests “informed consent documents and treatment agreements can be part of one document for the sake of convenience.” (22) This is echoed in the Indiana Task Force report, which describes the physician’s role in discussing with the patient “an Informed Consent and Treatment Agreement,” and offering sample merged documents as appendices. We reject the MLBI, Indiana Task Force & FSMB position that informed consent and treatment agreements can be one and the same. The informed consent process facilitates patient autonomy through a physician-patient dialogue that both educates the patient about the available treatment options and their risks and benefits and allows for the creation of a negotiated treatment plan guided by the patient’s values and goals. Treatment agreements can include treatment goals as well, but also include roles and responsibilities of patients and providers and grounds for continuation or discontinuation of treatment. It is these more prescriptive aspects of the treatment agreement, which are imposed upon, rather than negotiated within, the relationship that radically diverge from an ethically appropriate informed consent process and threaten the

foundation of trust in the physician-patient relationship. Furthermore, as treatment agreements are promoted as a key to the risk management strategy and legal obligation for providers prescribing opioids, it is reasonable to project that merging these processes into already brief patient encounters will lead providers to prioritize the more self-directed (and self-protective) goals of describing patient obligations, the consequences of their noncompliance, and to seek procurement of the patient's signature on the agreement over the discussion which lies at the core of the informed consent process. This threatens not only to undermine the opportunity for patient education and a biopsychosocial approach to pain management, but also to increase the likelihood that patients will feel untrusted and stigmatized by their physician.

*Imbalanced Responsibilities.* In addition, treatment agreements which include obligations to submit to drug testing and pill counting overly emphasize the patient's obligations for compliance while minimizing the physician's responsibility in the dyad. Typical patient responsibilities in opioid treatment agreements include using medication safely, not "doctor shopping" and to submit to drug testing. The Indiana Task Force sample treatment agreement goes beyond the emergency rules, indicating that the patient also agrees to allow "my healthcare provider to contact any ... legal authority ... to obtain or provide information about my care or actions *if the [sic] he or she feels it is necessary*" [Endnote 9, at 86, italics in the original]. (23) This language raises significant questions about physician-patient privilege for patients with chronic pain. It also demonstrates that the fiduciary responsibility of the physician to the patient, as a care provider, may be subsumed to a role as a facilitator of law enforcement efforts. Conversely, the obligations of physicians are a relatively short list. The FSMB model policy only lists one: to be available to patients for problems or for prescribing scheduled refills. The Indiana emergency rules only require physicians to regularly schedule appointments. Notably, nowhere in this discussion of obligations on the part of physicians is patient education, nondiscrimination, non-abandonment clauses or any other ethically appropriate or responsible behavior.

### **New Problem, Old Solution: A Return to Informed Consent**

The informed consent process in pain management must continue to be a simple process of communication and declaration of treatment preferences. It ought not to be conflated with blanket consent for drug testing, revocation of treatment for non-compliance or an open invitation to law enforcement. Put simply, the consent to treatment cannot also include agreement to non-treatment and still be logical. Informed consent must remain separate and wholly distinct from law enforcement action, at a minimum, and from discussions about grounds for terminating the physician patient relationship.

Our position is consistent with the American Pain Society/American Academy of Pain Management "Clinical Guidelines for the Use of Chronic Opioid Therapy for Chronic Non-Cancer Pain" which emphasize the need for "a continuing discussion with the patient regarding chronic opioid therapy [which] should include goals, expectations, potential risks, and alternatives." (24) This guidance leaves optional a written agreement or plan but notably describe such a plan as "patient *and clinician* responsibilities and expectations" (emphasis added) which can be utilized both for documentation and for patient education.

It is this emphasis on mutually shared decision-making in the management of chronic pain which is lacking from the MLBI and FSMB approaches.

Moreover, embracing a robust informed consent process which emphasizes the mutual responsibilities of physicians and patients is possible, even in the context of a public health crisis and law enforcement scrutiny. Even in this environment, providers must hold fast to the trust that is inherent and necessary in their relationships with patients and emphasize the informed consent process, rather than the contractual elements of the encounter. Even where documentation is required (as it is in Indiana and many other states), those processes should be the start of the conversation rather than the end of it.

## **Conclusion**

It is essential that the physician-patient relationship not be subverted in the name of public health or law enforcement, even in the midst of a prescription opioid epidemic. Universally mandating treatment agreements with mandatory compliance requirements for patients prescribed opioids outside of hospice or palliative care settings is neither evidence-based nor consistent with respecting the necessary trust between physician and patient. Maintaining a robust informed consent process that is separate from treatment agreements in pain management will ensure that the physician-patient relationship remains dependent upon trust, not contract enforcement.

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